HQ U.S. Air Force Academy

Integrity - Service - Excellence

USAFA Institutional Review Board (IRB)

Preparing Your Research Protocol

HQ USAFA/XPR

INSTITUTIONAL REVIEW BOARD

- **IRB is charged to protect the rights & welfare of human subjects in research**
  - **Authority and requirements for USAFA IRB derive from Federal law, DoD & AF policy**
  - **IRB has the authority to approve, require modifications or disapprove human research**
  - **Approved research is subject to continuing IRB review**
- **Administrative agent for IRB is USAFA/XPR**

Regulations

- **Authority and requirements derive from**

Federal law	DoD
32 CFR 219[1]	**DoDD 3216.2**
10 USC 980	

Air Force	USAFA
AFPD 40-4	**USAFA Sup _1**
AFI 40-402	**to USAFI 40-402**

[1] The "Common Rule." Parallel to 45 CFR 46 for Dept HHS

The IRB Process

- **Prepare package using protocol outline and informed consent document template (templates on IRB Web Page)**
  - **Submit for department coordination**
  - **If there is a survey in the study, get approval and survey control number from USAFA/XPA, 333-6481**
- **Preliminary review by USAFA/XPR**
- **IRB review**
  - **Complete modifications if required**
- **Approval by USAFA/CV**
- **Approval by HQAF/SGRC for greater than minimal risk studies**
- **Begin data collection!**

IRB Review Process

- Protocols distributed to IRB 10 days before meeting
  - PI may be contacted by reviewers with questions/clarifications
- Protocol summarized at board meeting followed by discussion and vote
  - Protocol can be approved, approved w/modifications, tabled or disapproved
- Board meetings are open and PIs are encouraged, but not required, to attend

Criteria for IRB Research Review

- Risks to subjects are minimized by using sound research design
- Risks to subjects are reasonable in relation to anticipated benefits to subjects and the importance of the knowledge to be gained
- Selection of subjects is equitable
- Informed consent is sought and documented

Criteria for Research Review (Cont.)

- Research provides adequate provisions for safety of subjects and monitoring of data
- Research provides adequate provisions to protect the privacy of subjects and maintain confidentiality of data
- Safeguards are in place to protect the rights and welfare of “vulnerable” research populations

Informed Consent

- **Assures that subjects:**
  - **Understand the nature of the research and can knowledgeably and voluntarily decide to participate**
- **Cadets present a "doubly" vulnerable research population; subject to undue influence as:**
  - **Student: Student-teacher relationship, grades, competitive selection**
  - **Military member: Cadet-officer influences, upperclass-underclass influences, class loyalty**

Criteria for Informed Consent Review

- Description of study
  - Purpose, duration, procedures, compensation/costs
- Description of risks
  - Reasonably foreseeable risks, discomforts
- Description of benefits
  - Direct benefits to subject
- Disclosure of alternatives
  - Same benefits/treatments available elsewhere?
- In case of an injury
  - Who to contact for medical or dental care

Informed Consent Review (Cont.)

- Occurrence of Unanticipated Adverse Event
  - Who will be contacted
- Extent of confidentiality
  - How will data be protected
- Compensation or treatment for injury
  - Only for studies with greater than minimal risk
- Contact for questions
  - Research, subject rights, research injury
- Voluntary participation statement
  - Can withdraw at any time w/o loss of benefits

Tips to Speed IRB Approval

- Identify problem areas through early discussions with IRB members or experienced researchers
- Use outlines & templates from IRB web page
  - Satisfies federal requirements and updated frequently
- Use minimum number of subjects needed to meet research goals
  - Justify subject requirements with power analysis or prior literature

Common IRB Pitfalls

- Using technical jargon in protocol and informed consent document
- Introducing verbal changes at the IRB meeting
- Failure to include subject recruitment material
- Using only subject populations of “convenience”
- Failure to recognize sources of undue influence in subject recruitment, selection and participation
- Inadequate or over-extended data protections
- Keeping data for longitudinal research w/o consent

After Your Research is Approved

- Ensure research complies with human subjects protections and is conducted IAW approved protocol
  - Modifications require IRB approval prior to implementation
- Monitor research & activities of associate investigators
  - “Adverse events” immediately reported to IRB
  - Significant changes to risk/benefit reported to IRB
- Provide continuing review and final reports
- Submit signed informed consent documents to XPR (for archiving) with the continuing review report

IRB Resources

- **Guidelines and instructions available from:**
  - **USAFA IRB web site: www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm**
  - **USAFA IRB Administrator (XPR, 333-6593) or IRB Chair (333-6740)**
  - **IRB members, Dept. research directors & mentors, and Federal, DoD and AF policy documents (policy documents on web page)**

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